

Remarks/Arguments

Status of Claims

Claims 2-6, 8 and 9 are pending in the application and are under substantive examination. Claims 3, 6, 8 and 9 remain rejected under 35 USC §112. Claims 2, 4 and 5 have been determined to recite allowable subject matter.

The claims recite a genus of isolated nucleic acids which are at least 96% identical to SEQ ID NO:1 and which encodes a simian ORL-1 receptor protein which binds nociceptin. The claims also recite a variant of SEQ ID NO:2 as well as methods of screening compounds for ORL1 activity.

Claim Amendment(s)

Claims 2-4, 6, 8 and 9 have been amended in a manner which adopts the examiner suggestions, and which in Applicants' opinion put all of the pending claims in condition for allowance. Support for the claim amendments can be found generally in the specification and claims as filed, particularly in Figures 2 and 3 and paragraphs 0065-0069.

No new matter has been added by way of the above-described claim amendments.

The Rejections to Claims 3, 6 and 9 Under 35 USC §112, First Paragraph Have Been Obviated

Claims 3, 6 and 9 remain rejected under 35 USC §112 first paragraph, for the reasons of record on pages 3-4 of the Office Action mailed May 1, 2008.

The Examiner notes that claims 3 and 9 recite that the nucleotide sequence is at least 96% identical to SEQ ID NO:1 and alleges that the breadth of the claim is excessive because Applicants have not provided a functional limitation that identifies the encoded protein as a simian ORL-1 receptor, or as an ORL-1 receptor in general. The Examiner suggests that recitation of a limitation/step reciting a functional limitation, such as requiring that the encoded protein binds nociceptin could obviate the remaining scope of enablement rejection.

Claims 3 and 9 have been amended in a manner that is consistent with the Examiner's suggested recitation of a functional limitation/step. More specifically, the claims have been amended to recite a limitation requiring the protein encoded by the nucleic acids encompassed by the claims bind nociceptin.

As amended, Claim 3 reads:

3. An isolated simian nucleic acid consisting of the nucleotide sequence set forth in SEQ ID NO:1 or a nucleotide sequence at least 96 % identical to SEQ ID NO:1 *wherein said nucleic acid encodes a protein which binds nociceptin* (emphasis added).

As amended claim 3 recites a functional limitation which defines the scope of the claimed subject matter as nucleic acids having a defined structure and function, including nucleic acids encoding the simian ORL1 receptor disclosed and claimed by the instant application.

As amended, Claim 9 reads:

9. A Compound evaluation method comprising:

- a) 1) transferring a simian Opioid receptor-like 1 gene comprising a nucleotide sequence consisting of the nucleotide sequence listed as SEQ ID NO:1, or a nucleotide sequence at least 96% identical to SEQ ID NO:1 *wherein said nucleotide sequence encodes a protein which binds nociceptin*, into a cell to prepare an isolated transformant cell expressing the ORL1 gene,
2) contacting a test compound with the cell, and
3) detecting specific binding of the test compound to a protein obtained by expression of the gene; or
- b) 1) transferring a simian Opioid receptor-like 1 (ORL1) gene comprising a nucleotide sequence consisting of the nucleotide sequence listed as SEQ ID NO:1, or a nucleotide sequence at least 96% identical to SEQ ID NO:1 *wherein said nucleotide sequence encodes a protein which binds nociceptin*, into a cell to prepare [[a]] an isolated transformant cell expressing the ORL1 gene,
2) contacting a test compound with the cell,
3) assaying the activity of an intracellular signal transducer produced by the contact between the cell and the test compound, and
4) comparing the activity with the activity of the intracellular signal transducer without contact with the test compound; or
- c) 1) contacting a test compound with an isolated simian protein comprising the amino acid sequence listed as SEQ ID NO:2 with a substitution, deletion, addition or insertion of one, or between 2 and 6 amino acids, *wherein said simian protein binds nociceptin*, and
2) detecting a change in activity of the protein caused by the contact between the protein and the test compound.

The premise of an enablement rejection based on the scope of Claim 9 has been overcome by virtue of this amendment which limits the scope of the screening method to *in vitro* methods which utilize isolated transformant cells which comprise a nucleotide sequence consisting of the nucleotide sequence listed as SEQ ID NO:1, or a nucleotide sequence at least 96% identical to SEQ ID NO:1 *wherein said nucleotide sequence encodes a protein which binds nociceptin*.

In light of the above-described claim amendments, Applicants respectfully request that the outstanding rejection of claims 3, 6 and 9 Under 35 USC §112, first paragraph be reconsidered and withdrawn.

The Rejection of Claims, 8 and 9 Under 35 USC §112 Second Paragraph Have Been Obviated

Claims 8 and 9 remain rejected under 35 USC §112, second paragraph for recitation of the phrase "ORL1 activity;" for reasons already of record on page 6 of the Office Action mailed May 1, 2008.

In order to expedite allowance of the claims determined to recite allowable subject matter, Applicants have amended claims 8 and 9 to avoid recitation of the term "ORL1 activity." Therefore, the outstanding indefiniteness rejections have been obviated.

As amended, Claim 8 reads:

8. An isolated protein comprising the amino acid sequence set forth in SEQ ID NO:2, or a protein comprising the amino acid sequence set forth in SEQ ID NO:2 with a substitution, deletion, addition or insertion of one, or between 2 and 6 amino acids, *wherein the protein binds nociceptin*.

As amended, the subject matter of claim 8 is clearly defined as isolated simian ORL-1 receptor proteins characterized by particular structural and functional limitations.

As indicated above, Claim 9 has also been amended to recite structural and functional limitations to describe the simian ORL-1 nucleic acids (elements a and b) or proteins (element c) used in the compound evaluation method that is disclosed and claimed in the instant application. For example, as amended, element (a) of claim 9 recites an assay which includes the step of:

- a) 1. transferring a simian Opioid receptor-like 1 gene comprising a nucleotide sequence consisting of the nucleotide sequence listed as SEQ ID NO:1, or a nucleotide sequence at least 96% identical to SEQ ID NO:1 *wherein said nucleotide sequence encodes a protein which binds nociceptin*, into a cell to prepare an isolated transformant cell expressing the ORL1 gene.

A review of the marked-up amended claim set provided on pages 2 and 3 of this submission makes it apparent that elements (b) and (c) of Claim 9 have been similarly amended.

In light of the above-described claim amendments, Applicants respectfully request that the outstanding indefiniteness rejections of claims 8 and 9 Under 35 USC §112, second paragraph be reconsidered and withdrawn.

Summary

For the reasons set forth hereinabove, Applicants respectfully believe that all of the pending claims are in condition for allowance and request that the Examiner reconsider and withdraw the remaining rejections and earnestly solicit allowance of the pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone her at the number provided below.

Respectfully submitted,

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Date: December 4, 2008